## REMARKS

Reconsideration and allowance in view of the foregoing amendments and the following remarks is respectfully requested. Upon entry of the present amendment, claims 1-4, 6, 7, 10, 12, 13, 15-17, and 19-39 will be pending. Claims 5, 8, 9, 11, 14, and 18 were previously cancelled. Claims 23-39 have been added to further distinguish the present invention over the prior art of record. To preserve the arguments presented in the previous response, the Applicant once again reasserts that the Examiner has not established the prima facie case of obviousness. Secondly, the Applicant rebuts the prima facie case of obviousness through the submission of declarations and documents which establish that an embodiment of the present invention has achieved surprising commercial success, resolves a long-felt need in the medical industry, and is being copied by a competitor.

1. Failure to Establish a Prima Facie Case of Obviousness

Claims 1-4, 6, 7, and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 4,054,207 to Lazure et al. in view of the Blass et al. article, the Stevens et al. article dated 1997 ("the Stevens 1997 article"), the Stevens et al. article dated 1999 ("the Stevens 1999 article"), the Franck article, U.S Patent No. 3,654,746 to Beckers, and U.S. Patent No. 4,597,242 to Hendriks et al. In addition, claims 12, 13, 15-17, 19, and 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Blass et al. in view of Stevens et al. (1999), Stevens et al. (1997), and Franck, in further view of Lazure, Beckers, and Hendriks. Applicant respectfully traverses these rejections for the reasons presented below.

Independent claim 1, recites an individual packaged solution for use in conjunction with a planned medical procedure on a neonatal infant. The packaged solution includes a cup-shaped container having a cavity defined therein opening to a mouth. A volume of a solution comprising sucrose and water is disposed within the cavity. The solution comprises about 10% to about 50% sucrose, with a remainder of the solution comprising water. A cover is

disposed over the mouth and seals the solution within the cavity. The solution and an interior of the container are in an aseptic state.

As enacted, 35 U.S.C. § 103 of the 1952 Patent Act states the following:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. The examiner bears the initial burden to present a prima facie case of obviousness.

It is then left to the applicant to rebut the prima facie case. In re Oetiker, 977 F.2d 1443, 24 USPQ 2d 1443, 1447 (Fed. Cir. 1992). It is generally accepted that the prima facie case of obviousness is established when the examiner can provide:

1. one or more references
2. that were available to the inventor,
3. that teach
4. a suggestion to combine or modify the references,
5. the combination or modification of which would appear to be sufficient to have made the claimed invention obvious to one of ordinary skill in the art.

An applicant who is able to prove that the examiner has failed to establish any one of these elements will overcome the examiner's prima facie case of obviousness.

In the present Application, the Applicant has argued unsuccessfully that the Examiner has not adequately established that the cited references teach or suggest the claimed invention. Therefore, the proposed combination of references could have only resulted from the improper use of hindsight.

The Federal Circuit has outlined the boundaries of obviousness in several significant decisions. In one such decision, Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co., 730 F.2d 1452, 221 USPQ 481 (Fed. Cir. 1984), a patent was filed on a hydraulic scrap shear. Two different shears were common in the industry: one for light to medium gauge metal and one for high gauge metal. The patent disclosed a device that was

capable of processing both types of scrap in a single moderately sized device. The District Court concluded that the patent ". . . disclosed and claimed a combination of features previously used in two separate devices." Id. at 1462. In reversing the District Court, the U.S. Court of Appeals for the Federal Circuit, was clear that this "fact alone is not fatal to patentability." Id. Even though all of the elements of the device were admittedly "old" and "well-known" in the scrap industry, the Federal Circuit concluded that combining these features into a single device was not obvious. Id. Although the claimed invention may employ known principles, this does not in itself establish that the invention would have been obvious. Id. Despite the clear desirability and commercial advantages of a single moderately sized scrap shear, the industry continued to process light and medium gauge metal separately from high gauge metal. It defies logic that the industry would have continued to do so if there truly was a "obvious" solution.

Just as in Lindemann, the elements of the claimed invention of the present application have been cobbled together by the Examiner admittedly old and well-known elements. On page 3, lines 1-8 of the Office Action, the Examiner asserts that "each of the features of the invention were 'notoriously old' and 'well-known' and that all that is missing is a single reference which teaches packaging the sucrose solution in the cup-shaped container." Although this observation is accurate, it is the same situation as in Lindemann. The prior existence of the elements of a claim does not render the claim obvious. The Examiner is correct to point out that a single reference reciting all the elements is not needed and would be a 35 U.S.C. § 102 rejection rather than a 35 U.S.C. § 103 rejection. However, the Examiner's burden of proof is higher than merely locating each element of the claim somewhere in the prior art. As best articulated by the former Chief Judge of the Federal Circuit, "virtually all inventions are 'combinations', and . . . every invention is formed of 'old elements' . . . . Only God works from nothing. Man must work with old elements." H.T. Markey, Why Not the Statute?, 65 J. Pat. Off. Soc'y 331, 333-34 (1983). The Examiner has failed to present any prior art reference which suggests combining or modifying the references as proposed by the Examiner. For this reason alone, the Examiner has failed to establish a prima facie case of obviousness.

Passage of time exhibits a trend away from the present invention

The Federal Circuit has held that it is proper to consider the "trend" in the art to show the obviousness of the inventor's solution. Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 139 F.3d 877, 45 USPQ2d 1977 (Fed. Cir. 1998). In this case there is a trend away from the present invention. The Lazure et al. reference was filed in 1976 and the Blass et al. article was submitted for publication in 1989. The Examiner claims that the Applicant's invention is obvious to one of ordinary skill in the art, and yet is unable to present any reference that suggests the proposed modification or combination. For at least 15 years, hospitals and pharmacies, even though they were aware of the analgesic effect of sucrose, have chosen to hand mix analgesic agents and subject newborn infants to potentially inconsistent and unsanitary agents. This, if anything, exhibits a trend away from the present invention. It defies logic to conclude that these skilled health care providers would continue utilizing an inefficient and potentially hazardous process if there was an "obvious" solution.

Mere recognition of the problem exhibits patentability

As articulated by the CCPA, "a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the 'subject matter as a whole' which should always be considered in determining the obviousness of an invention under 35 USC 103." In re Nomiya, 509 F.2d 566, 184 USPQ 607, 612 (C.C.P.A 1975). As discussed above, the Examiner has failed to demonstrate any suggestion or motivation to make the proposed combination. Moreover, this deficiency is for good reason and can be easily explained. No one even recognized the problem let alone a solution. This is further proof that the present invention is non-obvious.

In the Final Office Action dated January 5, 2005, the Examiner stated that the arguments on page 8 of the response (and presented again above) are concerned with anticipation. Yet, page 8, and this response on pages 9-11, recites the Lindemann case, and argues that the art when taken as a whole does not suggest and, if anything, teaches away from the present invention. Therefore the present invention cannot be deemed obvious. The

Lindemann case outlines the often cited principle that the claimed invention must be considered as a whole and that the prior art must suggest the desirability, and thus the obviousness, of making the combination. Lindemann, at 1462. It is perplexing how the Examiner has concluded that the Applicant's response did not adequately address obviousness.

Secondly, the Examiner's conclusion of obviousness seems best summarized by the following quote. The Examiner states at Page 3 of the Office Action that the prima facie case has been established by evidence that ". . . the applicant is not the first to provide food and medicines in single serve cup shaped containers; applicant is not the first to provide foods and medicines in aseptic packages and applicant was not the first to provide sterile sucrose solutions in the recited concentration as an analgesic to be administered orally to newborns." Once again, the Examiner's statement is correct; yet, these individual teachings still do not render the present invention obvious on their own. The claims are not broadly directed to all foods and medicines in any single serve container, to all aseptic packages, or to all sterile sucrose solutions. Such a broad claim was simply not presented. Moreover, the Examiner has failed to present any evidence that there is a suggestion to combine these teachings as proposed.

The Applicant contends that the Examiner has not met the burden to present a prima facie case of obviousness because there is no suggestion of the proposed combination, and there is not even any recognition of the problem. Instead, the Examiner appears to have given significant weight to the fact that the invention involves the combination of well-know elements and used inappropriate hindsight to cobble together the Applicants invention. Accordingly, the Applicant respectfully requests the Examiner to reconsider the rejection to claims 1-4, 6, 7, 10, 21, and 22.

The Examiner also rejected claims 12, 13, 15-17, 19, and 20 under 35 U.S.C. § 103. Independent claims 12 and 17 recite a method for administering a solution for use in conjunction with a planned medical procedure on a neonatal infant using a solution contained in aseptic single-use containers. The Applicant contends that claims 12 and 17, as well as all claims dependent thereon, are allowable for the same reason as highlighted above in connection with claim 1.

2. Rebuttal of Prima Facie Case

Once the Examiner has established a prima facie case of obviousness, the burden shifts to the applicant to rebut with objective evidence of nonobviousness. The applicant may present evidence relating to any of the secondary considerations outlined in Graham v. John Deere Co., 381 US 1, 148 USPQ 459 (1966) such as commercial success, fulfilling a long-felt need, failure of others, copying by others, and unexpected results. In addition, later opinions have added additional secondary considerations such as later discovered unexpected properties of the claimed invention, licenses or industry acquiescence, and skepticism prior to invention by those of ordinary skill. In re Mayne, 104 F.3d 1339, 41 USPQ 2d 1451 (Fed. Cir. 1997); Arkie Lures, Inc. v. Gene Larew Tackle, Inc., 119 F.3d 953, 43 USPQ 2d 1294, 1297 (Fed. Cir. 1997); In re Dow Chem. Co., 837 F.2d 469, 5 USPQ 2d 1529, 1532 (Fed. Cir. 1988).

The Applicant contends that introduction of the present invention into the marketplace has been met with surprising commercial success, resolves a long-felt need in the industry, and has been copied by at least one competitor. The Applicant sells an embodiment of the invention disclosed and claimed in the present application under the trademark SWEET-EASE™. A copy of the sales brochure for the SWEET-EASE™ product was previously submitted.

Surprising Commercial Success

As outlined in the Declaration of Cathy N. Bush (previously presented), the SWEET-EASE™ product has had surprising commercial success. Ms. Bush compares the SWEET-EASE™ product with the HEEL HUGGER™ product. Both products are disposable, single-use products used on infants and sold by the Applicant. Even though the SWEET-EASE™ product has been in the industry for less than half as long, it achieved approximately six times as many sales in 2003. Ms. Bush attributes the surprising commercial success of the SWEET-EASE™ product to the fact that it provides a convenient, aseptically packaged container filled with a sucrose solution not previously available in the medical industry.

The Declaration of Ms. Bush was deemed by the Examiner as insufficient to overcome the prima facie case of obviousness. The Examiner states that it was unclear how effective the sole warmers were at providing pain relief. To provide some clarification, the sole warmers are another product used with infants and sold by the Applicant. The purpose is to warm the soles of patients' feet to make the insertion of needles during various procedures less difficult and time consuming. Although this product may provide some relief, it is not an analgesic. These are two different products sold by the assignee. The sole warmers were merely presented to provide a baseline for comparison purposes. Of course, it would desirable to be able to compare the SWEET-EASE™ product with another comparable product. Unfortunately, the Applicant does not sell another packaged sucrose solution assembly. Rather than being used as a justification for discounting the persuasiveness of Ms. Bush's Declaration, it further exhibits the non-obviousness of the present invention.

Long-felt need

The present invention fulfills a long-felt need in the industry. As described in the declarations (previously presented) of Don T. Granger, M.D., Neal Guttenberg, M.D., and M. David Yohannan, M.D. ("Physicians' Declarations"), hand-mixing sucrose solutions have been undesirable. Doing so may contaminate the solution, result in wasted time, and the creation of inconsistent solutions. This has been the status of the art for at least 15 years. Accordingly, it is clear that the present invention addresses a problem that has defied resolution. The Physicians' Declarations describe the state of the art before introduction of the SWEET-EASE ™ product and the long-felt need of neonatologists. The Physicians' Declarations also describe the impact that the SWEET-EASE™ product has had on the medical industry. The Physicians' Declarations, previously submitted, are merely a small sample of the declarations that the Applicant could provide. It should be noted that the Applicant could produce additional declarations if the Examiner requires additional support.

Copying by Others

It has recently come to the attention of the assignee of the present invention that at least one other company has begun advertising the availability of a product that is a copy of the Applicant's invention. As noted on the attached advertisement, Hawaii Medical, LLC advertises the availability of a product called the TootSweet ™ 24% sucrose solution. The advertisement, among other things, states that this product ". . . helps to calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination." This is the same solution, in the same concentration, sold for the same purpose. Copying by others is yet another factor the Examiner is required to consider. To further clarify the scope of the present invention, the Applicant has also added new claims 23-39. Consideration and allowance of these new claims is requested.

In light of the above noted secondary considerations in conjunction with the attached supporting declarations and documents, independent claims 1, 12, and 17, as well as all claims dependent thereon, overcome the Examiners rejection based upon 35 USC § 103. In addition, the Applicant asserts that new claims 23-39 are novel and non-obvious over the prior art of record. Since all objections and rejections having been fully addressed, it is respectfully submitted that the present Application is in condition for allowance and notice of allowance is earnestly solicited.

Respectfully submitted,

By _____

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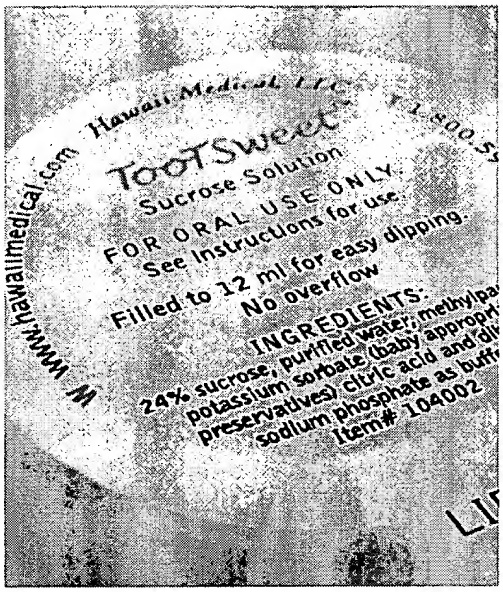
1010 Murry Ridge Lane
Murrysville, PA 15668-8525

Hawaii Medical

# TootSweet™
## 24% Sucrose Solution

Economical and Convenient...TWO-Year Shelf Life!

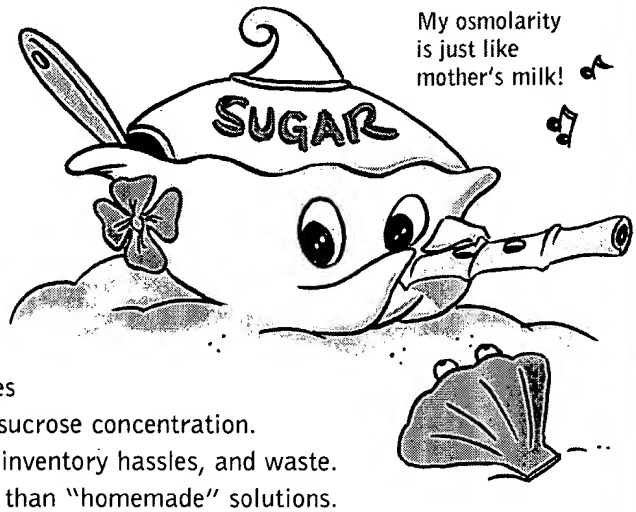
- Economical and easy to use
- No refrigeration required
- Easy pacifier dipping – no tipping
- Stable container materials prevent changes in sucrose concentration
- Two-year shelf life




THE LARGE TOOTSWEET CUP ALLOWS EASY DIPPING OF OUR GUMDROP PACIFIER. PLENTY OF EXCESS SPACE ELIMINATES OVERFLOW.

Now there's a safe, convenient way to deliver sucrose solution to your babies – *TootSweet*™ 24% sucrose solution. TootSweet helps calm and soothe babies in distress and during painful procedures, while protecting against bacterial contamination.

- For preemie and full-term babies.
- Baby-appropriate preservatives prevent bacterial growth.
- Osmolarity buffered to range of mother's milk (260 mOsm/kg).
- 12 ml in a 30 ml cup. Single patient use.
- Large cup for easy pacifier dipping or transfer into an oral syringe for dose splitting (single patient use only) without spills.
- Stable container material keeps formulation consistent, eliminates evaporation, prevents increased sucrose concentration.
- Two-year shelf life reduces cost, inventory hassles, and waste.
- More economical and consistent than "homemade" solutions.




TootSweet™

## Keep Babies Safe and Save Your Hospital Money with Easy-to-Use TootSweet™!

Sucrose is a proven, effective method of helping to calm and soothe babies. It is also an ideal medium to grow bugs! Contamination can occur from airborne bacteria, contact with oral flora from re-dipped pacifiers or mucosal contact with oral syringes. Independent studies found non-preserved 24% sucrose became highly contaminated (53 large colonies, and small colonies too numerous to count) with bacteria and mold in a matter of hours after contact with a pacifier used by an infant. (Copy of report available on request.)

## TootSweet's Baby-Appropriate Preservatives Prevent Bacterial Growth and Extend Shelf Life.

TootSweet is preserved with methylparben and potassium sorbate, preservatives in Ora-Sweet™, Gentamicin, Caffeine Citrate, and other products commonly administered to preemies and full-term babies. So you can have confidence TootSweet is safe, whether you administer it by dose-splitting in oral syringes, or when using a pacifier. We tested our formulation in accordance with USP Preservative Effectiveness Test (27 NF 22 2004). ISO certified Toxikon Testing Laboratory separately inoculated 20ml aliquots of TootSweet with 1.0 x 106 of the following organisms: Aspergillus nigar, Candida albicans, Escherichia coli, Pseudomonas aeruginos and Staphylococcus aureus. The test results met current USP criteria for Antimicrobial Preservative Effectiveness Test.

## Instructions for Use

TootSweet has a two-year shelf life in un-opened containers. TootSweet is single patient use. TootSweet may be administered by ORAL only syringe (label appropriately), or by pacifier dipping. And remember, always follow your hospital protocols for sucrose use. Just a couple of drops on a pacifier or on the tip of the tongue, a few minutes before a procedure, is sufficient.

PRODUCT SPECIFICATIONS:
1 oz cup containing 12ml of 24% sucrose in purified water.
0.022% methylparben and 0.073% potassium sorbate as preservatives.
Citric acid and dibasic sodium phosphate as buffers to adjust osmolarity.

## Ordering Information

Give your babies the comfort and convenience of TootSweet! To place an order, request a sample, or find out more, please call Tri-anim, our national distributor at 1.800.874-2646.

## TootSweet 24% Sucrose Solution

| ITEM# | DESCRIPTION | QUANTITY |
|---|---|---|
| 1040021 | 1oz cups with 12ml 24% sucrose solution | Box of 40 |
| 1040022 | 1oz cups with 12ml 24% sucrose solution | Case of 240 (6 boxes) |

## Other Great NICU Solutions from Hawaii Medical

- *GumDrop Pacifier™*
  Incredibly soft! Silicone covers entire surface. Low profile design. No trimming to fit nasal tubes!
- *LifeGuard™ Electrodes*
  Electrodes that last, even in high humidity incubators.
- *LilyPad™ Pressure Relieving Mattress*
  Keeps babies more comfortable. Economical. Clean and re-use. Doesn't stain!

- *NeatNick™*
  Sweeping action heel lancet makes a neater nick. Is less painful for your babies. Costs less, too!
- *Save the Gonads™ X-Ray Shields*
  The first x-ray shields designed for babies, from micro-preemies to full-term newborns.
- *Shell-O™ Gel Pillow and Positioning Aid*
  Affordable, long-lasting gel support for babies of all sizes.
- *SunFish™ Locking Temp Probe Cover*
  Designed to lock the temp probe wire in place.

## Call for Product Samples or More Information

Hawaii Medical products are available for order from our national distributor, Tri-anim. For questions, product samples, or the sales representative in your area, please call 1.800.874.2646.

*Aloha from Boston!*

*Hawaii Medical*
Innovating Medical Products For Kids

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